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BIO/DYNAMICS INC		
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INITIAL SUBMISSION: PRIMARY DERMAL IRRITATION STUDY WITH ACRYLATE ESTERS OF PENTAERYTHRITOL IN RABBITS WITH COVER LETTER DATED 051592		
Chemical Category		
ACYLATE ESTERS OF PENTAERYTHRITOL		

8(e)

4961

CAP

(COMPLIANCE AUDIT PROGRAM)

TSCA CONFIDENTIAL BUSINESS INFORMATION

ORIGINAL - DCO (Jeff/Eric)

COPY # 1 - CBIC

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COMPANY SANITIZED

ORIGINAL - PINS

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CONTAINS NO CBI

ORIGINAL - PINS

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CONTAINS NO CBI

RHÔNE-POULENC

RHÔNE-POULENC INC.

CN 5266, PRINCETON, NJ 08543-5266
TELEPHONE: (908) 297-0100 TELEX: 21106

May 15, 1992

8EHQ-0592-4267 init

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Document Processing Center (TS-790)
Attn: Section 8(e) Coordinator (CAP Agreement)
Office of Toxic Substances
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO.: RPS - 0093

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc (RPI, CN5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The enclosed report provides information on the following chemical substance:

Product Name: Sipomer PETA
Identity: Acrylate esters of pentaerythritol >99%

CAS Registry No: 3524-68-3

CAS Registry Name: 2-Propenoic acid, 2-(hydroxymethyl)-2[[(1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester

The title of the enclosed report is:

Primary Dermal Irritation Study in Rabbits

The following is a summary of the adverse effects observed in this report.

The material is a severe, irreversible primary dermal irritant. One death occurred. All animals exhibited necrotic skin. (pH Not available)

RPI does not claim any portion of the information in this submission to be TSCA confidential business information (TSCA CBI).

RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notification on the subject chemical substance.

In total, RPI is submitting three copies of the enclosed report and this cover letter: an original and two copies.

Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology at (919)549-2222 (Rhône-Poulenc, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,

Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
(609)860-3589

CEMjr/mm
Enclosures

CAP ID No. 5 OR-BAK-0433
Reviewed for Sec. 8 (e)
Compliance Program
On 9/12/91 By BAK

PETA
Pentaerythritol Tetracaprylate
Al. Co. Can PETA

Bio/dynamics Inc.

Division of Biology and Safety Evaluation

PROJECT NO.: 6280-80

PRIMARY DERMAL IRRITATION STUDY IN RABBITS

TEST MATERIAL: C-171

Submitted to: Celanese Corporation
New York, New York

Date: December 31, 1980

I. INTRODUCTION

This study was conducted for Celanese Corporation to evaluate the primary dermal irritation produced by C-171. The study was performed at Bio/dynamics, Inc., Mettlers Road, East Millstone, New Jersey 08873, and followed procedures based on the methods described in 40 CFR Part 163.81-5 (ENVIRONMENTAL PROTECTION AGENCY, PESTICIDE PROGRAMS. Proposed Guidelines for Registering Pesticides in the U.S.; Hazard Evaluation: Humans and Domestic Animals; Primary Dermal Irritation Study).

II. MATERIALS AND METHODS

A. Dates of Study:

Animal Receipt:	September 29, 1980
Initiation (Dosing):	October 21, 1980
Termination (Last Observation):	November 4, 1980

B. Study Personnel:

Study Director:	Carol S. Auletta, B.A.
Laboratory Supervisor:	Donna L. Blaszcak, B.S.
Technician-in-Charge:	Janet Erickson, B.S.
Study Monitor (Report Preparation):	Paula S. Hodge, B.A.

C. Test Animals: Albino Rabbits

Strain:	New Zealand White
Reason for Selection:	Standard laboratory animal
Supplier:	Dutchland Laboratory Animals Denver, Pennsylvania
Number:	Six (3 males, 3 females)
Age:	Young adults

II. MATERIALS AND METHODS (con.t)

Weight: (Pretest)	2.0 to 3.0 kilograms
Equilibration Period:	22 days
Observations:	All animals were checked for viability twice daily. Prior to assignment to study all animals were examined to ascertain suitability for study.

Husbandry:

Housing:	Individually housed
Cages:	Suspended, stainless steel
Environmental Conditions:	Temperature: monitored twice daily Temperature range during study: 63°-68°F Humidity: monitored daily Light cycle: 12 hours light, 12 hours dark
Food:	Purina Rabbit Chow, ad libitum
Water:	Automatic watering system, ad libitum Municipal water supply (Elizabethtown Water Co.)
Identification:	Each animal was identified with a monel ear tag bearing a unique number prior to testing.
Selection:	Animals considered unsuitable for study because of poor health or outlying body weights were excluded from selection. Animals for study were selected from those remaining.

D. Test Material:	C-171
Description:	Viscous clear liquid
Date of Receipt:	September 8, 1980
Received from:	Celanese Corporation
Storage:	Room temperature

Preparation of Dosing Material Mixtures:

Test material administered as received, no mixture was required.

II. MATERIALS AND METHODS (cont.)

E. Preparation of Animals

On the day before dosing (approximately 18 hours before dosing), the hair of each rabbit was closely clipped from the back with an electric clipper, so as to expose the back from the shoulders to the lumbar region. Just prior to dosing, the skin of the left side of each animal was abraded longitudinally every 2 or 3 centimeters over the area of exposure. Abrasions were deep enough to penetrate the stratum corneum, but not so deep as to disturb the derma or produce bleeding. The skin of the right side of each animal was left intact.

F. Administration of Test Material:

There were four test sites per animal, two on either side of the spinal column. The two sites on the left side were abraded while the two sites on the right side were left intact. 0.5 mls of the test substance was applied beneath a surgical gauze square, 1"x1", eight single layers thick, placed directly on the test site. Once the substance had been applied to the test site, the gauze square was held in place with Dermicel® tape. Plastic sheeting was then wrapped around the animals and secured with masking tape to retard evaporation and keep the test substance in contact with the skin without undue pressure. Elizabethan collars were then placed on the animals.

Following approximately 24 hours of exposure, the wrappings were removed and the test sites wiped free of excess test material. After 30 minutes, dermal observations were made.

G. Experimental Evaluation (In-Life):

Viability Check: Twice Daily

Evaluation of Skin Irritation:

Observations were made for erythema and edema or other evidence of irritation or injury 30 minutes after removal of the occlusive wrapping, i.e., approximately 24 hours after administration of the test material, approximately 72 hours after administration and daily thereafter through 14 days after dosing, or until no signs of irritation were present. Irritation still present after 14 days was considered indicative of permanent damage. The scoring scale used is presented in Appendix A.

H. Post Mortem:

A gross postmortem examination was performed on any animal which died spontaneously. All abnormalities were recorded but no tissues were saved.

II. MATERIALS AND METHODS (cont.)

I. Raw Data Storage:

All raw data and the original study protocol will be permanently retained on file at the Bio/dynamics Archives.

III. RESULTS

Dermal observations are presented in Table I; the scoring system used is presented in Appendix A.

The primary dermal irritation score for C-171, calculated as described in Appendix A, is 7.6.

One animal which exhibited an especially severe response at 24 hours (hypothermia, severe erythema and edema over entire back) was found dead at 72 hours. Necropsy observations (Appendix B) revealed thick green-black material in the stomach and multiple foci of black material adhered to the gastric mucosa.

All animals exhibited necrotic skin at all test sites from Day 5 through termination of the study (Day 14). Eschar formation and desquamation or fissuring also occurred at most sites from Day 9 through 14.

Carol S. Auletta 12/31/80
Carol S. Auletta, B.A. Date
Study Director

G. K. Hogan 12/31/80
Geoffrey K. Hogan, Ph.D. Date
Vice-President

TABLE I

PRIMARY DERMAL IRRITATION STUDY IN RABBITS

TEST MATERIAL: C-171

INDIVIDUAL DERMAL IRRITATION SCORES[a] - 24 AND 72 HOURS

Time Interval	Patch Sites & Observations		Animal Number and Sex 6207M	6209F	6208M	6210F	6233M	6214F	Mean Score
24 Hours	Left Front*	ER	4N[b]	3[c]	4N[d]	3	3[e]	4N	3.5
		ED	4	4	4	4	4	4	4.0
	Right Front	ER	4N	3	4N	3	3	4N	3.5
		ED	4	4	4	4	4	4	4.0
	Left Back*	ER	4N	3	2	3	3[e]	4N	3.2
		ED	4	4	4	4	4	4	4.0
	Right Back	ER	4N	3	2	3	2	4N	3.0
		ED	4	4	4	4	4	4	4.0
72 Hours	Left Front*	ER	[f]	4N	4N	4N	4N	4N	4.0
		ED		4	4	4	4	4	4.0
	Right Front	ER		3	4N	4	4N	4N	3.8
		ED		4	4	4	4	4	4.0
	Left Back*	ER		4N	4N	4N	4N	4N	4.0
		ED		4	4	4	4	4	4.0
	Right Back	ER		3	4N	4N	2	4N	3.4
		ED		4	4	4	4	4	4.0
								TOTAL:	60.4
								Primary Irritation Score (Total ÷ 8):	7.6

[a]Scored using scale presented in Appendix A.
[b]Animal had hypothermia and severe erythema and edema over entire back (6207M).
[c]Animal had soft stool (6209F).
[d]Animal had fecal staining (6208M).
[e]Erythema was a purplish hue.
[f]Animal died 10-24-80 (Day 3).
*Abraded skin
ER-Erythema
ED-Edema
N-Necrosis

TABLE I (cont.)

PRIMARY DERMAL IRRITATION STUDY IN RABBITS

TEST MATERIAL: C-171

INDIVIDUAL DERMAL IRRITATION SCORES[a] - DAYS 4 THROUGH 14

Animal No. and Sex	Patch Sites & Observation		Days 4	5	6	7	8	9	10	11	12	13	14
6209 F	LF*	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	3	3	3	3	3	3	3	3
		Other	N	N	N	N	N	N,E F	N,E F	N,E F	N,E F	N,E F	N,E F
	RF	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	3	3	3	3	3	3	3	3
		Other	N	N	N	N	N	N,E F	N,E F	N,E F	N,E F	N,E F	N,E F
	LB*	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	3	3	3	3	3	3	3	3
		Other	N	N	N	N	N	N,E F	N,E F	N,E F	N,E F	N,E F	N,E F
	RB	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	3	2	3	3	3	3	3	3
		Other	N	N	N	N	N	N,E F	N,E F,ex	N,E F	N,E F	N,E F	N,E F
6208 M	LF*	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	3	3	3	3	3	3	3	3
		Other	N	N	N	N	N,D	N,E D	N,E D	N,E D	N,E D	N,E D	N,E D,ex
	RF	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	3	3	3	2	2	2	2	2	2	2
		Other	N	N	N	N	N,D	N,E D	N,E D	N,E D	N,E D	N,E D	N,E D
	LB*	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	3	3	3	3	3	3	3	3	3	3
		Other	N	N	N	N	N,D	N,E D	N,E D	N,E D	N,E D	N,E D	N,E D
	RB	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	3	3	2	2	2	2	2	2	2	2
		Other	N	N	N	N	N,D	N,E D	N,E D	N,E D	N,E D	N,E D,ex	N,E D,ex

[a]Scores using scale presented in Appendix A.

LF-Left Front
RF-Right Front
LB-Left Back
RB-Right Back

ER-Erythema
ED-Edema
*Abraded skin
N-Necrosis

D-Desquamation
E-Eschar
F-Fissuring
ex-Exfoliation

TABLE I (cont.)

PRIMARY DERMAL IRRITATION STUDY IN RABBITS

TEST MATERIAL: C-171

INDIVIDUAL DERMAL IRRITATION SCORES[a] - DAYS 4 THROUGH 14

Animal No. and Sex	Patch Sites & Observation		Days 4	5	6	7	8	9	10	11	12	13	14
6210 F	LF*	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	3	2	2	2	2	2	2	2	2	2
		Other	N	N	N	N	N	N,E D	N,E D	N,E D	N,E D	N,E D	N,E D
	RF	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	3	3	2	2	2	2	2	2	2	2
		Other	-	N	N	N	N	N,E D	N,E D	N,E D	N,E D	N,E D	N,E D
	LB*	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	3	3	3	2	2	2	2	2	2	2
		Other	N	N	N	N	N	N,E D,F	N,E D	N,E D	N,E D	N,E D	N,E D
	RB	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	3	3	3	2	2	2	2	2	2	2
		Other	N	N	N	N	N	N,E D	N,E D	N,E D	N,E D	N,E D	N,E D
6233 M	LF*	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	4	3	3	3	3	3	3	3
		Other	N	N	N	N	N,E	N,E D	N,E D	N,E D	N,E D	N,E D	N,E D
	RF	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	4	3	3	3	3	3	3	3
		Other	N	N	N	N	N	N,E D	N,E D	N,E D	N,E D	N,E D	N,E D
	LB*	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	4	3	3	3	3	3	3	3
		Other	N	N	N	N	N	N,E D	N,E D	N,E D	N,E D	N,E D	N,E D
	RB	ER	3	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	4	3	3	3	3	3	3	3
		Other	-	N	N	N	N,E	N,E D	N,E D	N,E D	N,E D	N,E D	N,E D

[a]Scores using scale presented in Appendix A.

LF-Left Front
RF-Right Front
LB-Left Back
RB-Right Back

ER-Erythema
ED-Edema
*Abraded skin
N-Necrosis

D-Desquamation
E-Eschar
F-Fissuring

TABLE I (cont.)

PRIMARY DERMAL IRRITATION STUDY IN RABBITS

TEST MATERIAL: C-171

INDIVIDUAL DERMAL IRRITATION SCORES[a] - DAYS 4 THROUGH 14

Animal No. and Sex	Patch Sites & Observation		Days 4	5	6	7	8	9	10	11	12	13	14
6214 F	LF*	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	4	4	4	4	4	4	4	4
		Other	N	N	N	N	N	N,E	N,E	N,E	N,E	N,E	N,E
	RF	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	4	4	4	4	4	4	4	4
		Other	N	N	N	N	N	N,E	N,E	N,E	N,E	N,E	N,E
	LB*	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	4	4	4	4	4	4	4	4
		Other	N	N	N	N	N	N,E	N,E	N,E	N,E	N,E	N,E F
	RB	ER	4	4	4	4	4	4	4	4	4	4	4
		ED	4	4	4	4	4	4	4	4	4	4	4
		Other	N	N	N	N	N	N,E	N,E	N,E F	N,E F	N,E F	N,E F

[a]Scores using scale presented in Appendix A.

LF-Left Front
RF-Right Front
LB-Left Back
RB-Right Back

ER-Erythema
ED-Edema
*Abraded skin
N-Necrosis

E-Eschar
F-Fissuring

DRAIZE[1] EVALUATION OF DERMAL IRRITATION

I. Dermal Observations

Erythema and Eschar Formation (Most severely affected area graded):

No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Edema Formation (Most severely affected area graded):

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond area of exposure)	4

II. Primary Irritation Index[2]

Mean scores per site (6 animals, four sites per animal) are calculated and summed as follows:

Erythema and eschar formation

Intact skin	- 24 and 72 hours	-	4 values
Abraded skin	- 24 and 72 hours	-	4 values

Edema formation

Intact skin	- 24 and 72 hours	-	4 values
Abraded skin	- 24 and 72 hours	-	4 values
		Total =	16 values

Sum of mean values ÷ 8 = Primary Irritation Index

[1]Draize, J.H. 1959. The Appraisal of Chemicals in Foods, Drugs, and Cosmetics, pp. 36-45. Association of Food and Drug Officials of the United States, Austin, Texas.

[2]Modified from method presented in Federal Hazardous Substances Act Regulations, 16 CFR 1500.

APPENDIX B

PRIMARY DERMAL IRRITATION STUDY IN RABBITS

TEST MATERIAL: C-171

DAY OF DEATH AND NECROPSY OBSERVATIONS

Animal No. and Sex	Day of Death	Type of Death[a]	Observations
6207 M	3	F	Stomach: pyloric region - hardened and thickened, contains green-black material, mucosa - adhering black masses, averaging 0.5 cm. in diameter; spleen: extremely small; skin on ventral surface extremely thickened.

[a]F=Found dead (Day given is day found dead).

CERTIFICATE OF AUTHENTICITY

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